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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,420	07/23/2003	Nancy Auestad	6960USP1	9175

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ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,420	AUESTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☒ Claim(s) 1-3 and 12 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 14 October 2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 are presented for examination.

Acknowledgement is made of Applicant's claim for priority under 35 U.S.C. 119(e) from provisional application number 60/401,466 filed August 6, 2002. The instant application is recognized as a continuation-in-part (CIP) of application number 10/602,169, now abandoned. Applicant's Information Disclosure Statement filed October 14, 2003 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449 (6 pages total), the Examiner has considered the cited references.

Claim Objection

Claims 1, 2 and 3 are objected to for failing to define the acronyms "PUFA", "DHA" or "AA", respectively, at the first occurrence in the claims. Claims 1, 2 and 3 should be amended to include the definitions of these acronyms accordingly.

Claim 12 is objected to for failing to define the abbreviation "CB_1" at the first occurrence in the claims. Claim 12 should be amended to include the definition of the abbreviation at line 1 of the claim.

Specification

The use of the trademark SIMILAC NEOSURE™ (Infant Formula) and SIMILAC SPECIAL CARE™ (Infant Formula) has been noted in this application at page 20, lines 25-26 of

the disclosure. Each instance should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

The disclosure is objected to because of the following informalities:

(i) the word "for" in the expression "For dry-filled..." at page 21, line 23 of the disclosure is misspelled;

(ii) the word "as" should be corrected to read "**and**" at page 23, line 4 of the disclosure for clarity; and

(iii) the word "and" should be corrected to read "**an**" at page 27, line 15 of the disclosure.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I Claims 5-6, 10-11, 16-17, 22-23, 26 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The MPEP sets forth the following at §2173:

> "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure

> of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (See MPEP §2173).

The term "about" in the expressions "about 8 mg to about 396 mg/kg body weight" (claims 5, 10, 16 and 22) and "about 84 to about 15,832 mg" (claims 6, 11, 17, 23, 26 and 29) is a relative term that renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In the present specification at page 25, lines 9-11, Applicant sets forth the following:

> "Throughout this application, numerical ranges given as "x-y" should be interpreted as "from about x to about y"; it being understood that "about" modifies both the value x and the value y."

Such disclosure, however, does not render the term definite. The term "about" would invite subjective interpretations of whether or not a particular dosage amount is included in or excluded from the present claims and what degree of variability outside the recited ranges is within the scope of the claims. Thus, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and, thus, the claims do not meet the requirements of 35 U.S.C. § 112, second paragraph.

II Claims 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The phrase "administering to at least some members of said population" in line 2 of present claim 18 is an expression that renders the claim indefinite. The phrase is not defined

by the claims and the specification does not provide any direction as to the number and/or identity of those members of the population to which the composition is to be administered. Thus, one of ordinary skill in the art would not be reasonably apprised on the scope of the invention.

As the MPEP sets forth in §2111.01, words and phrases in the claims must be given their plain meaning" as understood by one having ordinary skill in the art unless defined by Applicant in the specification with "reasonable clarity, deliberateness and precision" (See MPEP §2111.01). Here, Applicant has failed to define the number of members of a population, what proportion of a population is encompassed by the phrase "at least some members of said population", or even what population is intended to be within the scope of the claims and is, therefore, not reasonably clear, deliberate or precise. The lack of a definition in order to determine the number or proportion of members intended by the phrase or a description of the population intended to be within the scope of the present claims does not provide sufficient disclosure as to how one skilled in the art would determine what is intended to be within the scope of the present claims. Thus, the identity of those members included or excluded by the phrase "at least some members" is open to subjective interpretation and such is inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph.

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. 102, a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps*

Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1001 (Fed. Cir. 1991); *In re Donahue*, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). In order to anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q.1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). In order to inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile,* 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Jandacek et al. (International Publication No. WO 02/00042 A2; January, 2002). Jandacek et al. teaches the use of a composition comprising a satiety agent, such as a long chain fatty acid, including docosahexaenoic acid, linoleic acid, alpha-linolenic acid, arachidonic acid or eicosapentaenoic

acid or mixtures thereof (see page 6, lines 23-33 for a detailed description of satiety agents taught by the reference) administered "prior to subsequent consumption of food so as to induce a sensation of satiety in the subjects for a sufficient time wherein the amount of food subsequently consumed in reduced, thus reducing total caloric intake by controlling the subject's appetite" (page 6, lines 18-22) in a method for managing the body weight of humans (page 7, lines 21-24) and controlling appetite (page 7, lines 32-33). Jandacek et al. also teaches administration of the disclosed composition at a dose of 0.01 g/kg body weight to about 10.0 g/kg body weight. The composition may be administered "in any number of food forms including liquid beverages such as milk shakes, fruit juices or the like, solid food products such as bars or pharmaceutical dosage forms including compressed and molded tablets, soft and hard gelatin capsules, microcapsules, emulsions, and suspensions" (page 7, lines 14-18).

Jandacek et al. expressly states the use of a long chain fatty acid, including docosahexaenoic acid or arachidonic acid, as a satiety agent in the disclosed composition, or the use of mixtures of any one or more of the long chain fatty acids disclosed in the reference (page 7, lines 23-33). Because Jandacek et al. teaches the use of a long chain fatty acid individually or in combination with one or more other long chain fatty acids in order to produce a mixture, the disclosure of Jandacek et al. is considered to anticipate the use of DHA administered alone, "independent of AA" as recited in present claims 2, 14 or 20, **or** the use of DHA administered in combination with AA, as a mixture of long chain fatty acids, as recited in present claim 8.

The Examiner has noted that present claims 5-6, 10-11 and 22-23 are drawn to methods of treating an infant or child or adult. Since Jandacek et al. broadly discloses the use of the fatty acid composition in the modulation of appetite and the reduction of food intake for use in humans, the Examiner considers the reference to place the treatment of any human at various different stages of development, such as an infant, a child, an adolescent, or an adult, within the possession of the public. The reference is, therefore, considered to anticipate the limitations of "infant" or "child or adult" in the present claims.

Present claims 4, 9, 15 and 21 are drawn to methods comprising the administration of a long chain n-3 polyunsaturated fatty acid "during a growth phase prior to or in conjunction with an appetite-impacting stimulus" (see present claim 4, line 2, for example). The Examiner has noted that the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood. Therefore, because Jandacek et al. discloses the use of the fatty acid composition in the modulation of appetite and the reduction of food intake broadly for use in humans, the Examiner considers the reference to directly anticipate the claim limitation of "administered during a growth phase" because growth of the human body would be necessarily be present at **any time** the composition was administered. Furthermore, the Examiner has noted the phrase "appetite-impacting stimulus" and has interpreted the phrase, for the purpose of examination purpose, to include any stimulus that affects appetite or food consumption. For this reason, and in light of the teachings of Jandacek et al., who broadly discloses the use of the long chain fatty acid composition for appetite modulation and reduction of food intake prior to food consumption (page 6, lines 18-22), the Examiner considers the

presence of food to be an "appetite-impacting stimulus" because it affects appetite or food consumption. Therefore, claims 4, 9, 15 and 21 are properly rejected under 35 U.S.C. 102(a).

Jandacek et al. expressly teaches a dose of the satiety agent, or long chain fatty acid (see page 6, lines 23-33) of the disclosed composition, of about 0.01 g/kg body weight to about 10.0 g/kg body weight. Present claims 5, 10 and 22 are drawn to a long chain fatty acid dose of 8 to 396 mg/kg body weight, or 0.008 g/kg body weight to 0.396 g/kg body weight. Although Jandacek et al. teaches a lower limit of 0.01 g/kg body weight, the reference discloses that the dose may be "about 0.01 g/kg body weight", which accounts for a slight variation above or below the given limit. Such a variation of 0.002 g/kg body weight would have been in possession of the public in light of the teachings of Jandacek et al. and, therefore, because the dose range of the present claims is within the range taught by the reference, it is considered to be anticipated. See MPEP §2131.01 regarding rejections under 35 U.S.C. 102 for ranges.

Present claims 6, 11 and 23 recites "a daily amount of about 84 to about 15,832 mg" (see line 2 of claim 6, for example). Jandacek et al. expressly teaches an amount of the disclosed composition of the invention to be used in a dosage of 0.01 to 10 mg/kg body weight. Thus, for an average 70 kg adult human, the dose range taught by the reference would have been between 0.7 g and 700 g (or 700 mg to 700,000 mg). Therefore, although Jandacek et al. does not expressly teach a dose range of 84 mg to 15,832 mg, the dose range of the reference and the dose range recited in the present claims clearly overlap insofar as the present claim reads on 700 mg-15,832 mg and, thus, claims 6, 11 and 23 are is considered to be anticipated by Jandacek et al.

(See below under "Claim Rejections-35 U.S.C. 103" for further rejection of dose ranges under 35 U.S.C. 103).

Although Jandacek et al. does not expressly teach a method for decreasing the incidence of obesity or overweight status in a population of mammals, such a concept was placed in the possession of the public based on the disclosure of the reference. Jandacek et al. expressly teaches a method of modulating appetite and reducing food intake in the context of the use of natural materials in the management of body weight as a result of the prevalence of obesity and overweight status of the general population (see page 1-page 4, line 7). Therefore, the Examiner considers the concept of treating obese or overweight patients using the long chain fatty acid composition to be places in possession of the public by Jandacek et al. insofar as the reduction of obesity or overweight status by modulating appetite and reducing food intake is achieved by the administration of the claimed active agent. Claims 18-23 are, therefore, properly rejected under 35 U.S.C. 102(a).

Rejection of Claims 12-17 and 24-29 Based on Inherency

It is recognized that the prior art teachings of Jandacek et al. do not expressly recite that the use of a long chain n-3 polyunsaturated fatty acid, such as DHA, has an antagonistic effect on the cannabinoid-1 (CB_1) receptor in the brain or that it increases serum leptin levels, but the reference does, however, teach a method of modulating/controlling appetite and reducing food intake by the administration of a long chain fatty acid composition comprising any one or more fatty acids, including DHA (see page 6, lines 18-22, page 7, lines 21-24 and page 7, lines 32-33,

for example). However, because the particular method steps and compounds that are present in the instant claims are also in the patent, it is deemed that the antagonism of the CB_1 receptor and the increase in serum leptin levels using an amount of the composition of the prior art would have been inherent, whether recognized by the patentees or not. The claiming of a new use, new function or **unknown property** that is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 U.S.P.Q. 430, 433 (CCPA 1977). See also MPEP §2112. It is irrelevant that the prior art observers did not recognize the property or function of the disputed claims; if the prior art inherently possesses that characteristic, it anticipates. Applicant's attention is further drawn to the MPEP at §2113, which states, "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Thus, claims 12-17 and 24-29 are properly rejected as being anticipated by Jandacek et al. The Examiner notes that claims 17, 26 and 29 are rejected as being anticipated by Jandacek et al. insofar as they read on a dose range of long chain n-3 fatty acid of 700-15,832 mg.

Further Rejection of Claims 12-17 and 24-29 under 35 USC § 103 is NOT Proper

A subsequent rejection under 35 U.S.C 103 will not be made against claims 12-17 and 24-29 because under the present set of facts, the concept of inherency dictates against making such rejections.

In particular, it has been held that inherency must be a necessary result and not merely a

possible result. *In re Oelrich* (CCPA 1981) 212 U.S.P.Q. 323. Here, if the Examiner were to conclude that the use of the claimed active agent at the claimed dose range in a host not specifically taught by the reference "would have been obvious", such a conclusion would be, in essence, creating a possible host and, thus, not a host that necessarily exists in the reference. If the host does not necessarily exist, logic dictates that any physiological function or drug effect that would be present in such a host would also be only a possible function or effect and most certainly not a function or effect that would be necessarily present.

As an example, claim 17 recites a dose range of long chain n-3 fatty acid of 84-15,832 mg in a method of antagonizing the CB_1 receptor by administering a long chain n-3 fatty acid. Jandacek et al. (WO 02/00042) teaches the treatment of appetite modulation and reduction of food intake comprising administering composition comprising a long chain fatty acid, such as DHA or others (see page 6, lines 23-33) at a dose of 0.01-10 g/kg body weight, or 0.7-700 g, or 700-700,000 mg for an average 70 kg human (see "Claim Rejections-35 USC §102"). Although the reference is silent as to the effect of a long chain n-3 fatty acid on the CB_1 receptor, such an effect is considered to be inherent to the claimed composition at the dose range anticipated by the prior art. However, the property is not inherent in the prior art disclosure for doses of the composition outside the range taught by the prior art because the disclosure of the use of 700 mg-15,832 mg for an average 70 kg human does not necessarily dictate the use of 84-699 mg of the claimed composition, for example, wherein concurrent antagonism of the CB_1 receptor would occur.

The Examiner is guided by the MPEP at §2112(IV), which states, "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art)" (emphasis added).

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jandacek et al. (International Publication No. WO 02/00042), for the reasons of record set forth above.

The differences between the Jandacek et al. reference and that of the presently claimed subject matter lie in that the reference does not teach:

(i) the presently claimed dose range of long chain n-3 fatty acid from 84-699 mg as recited in present claims 6, 11 and 23.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) The determination of the optimum dosage regimen to decrease or modulate appetite or decrease obesity or overweight status with the presently claimed active agent would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors. These would have included the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage regimen that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan.

Conclusion

Rejection of claims 1-29 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

March 10, 2005

RAYMOND HENLEY III
PRIMARY EXAMINER
AU1614